

REMARKS/ ARGUMENTS

Applicant has carefully studied the final Examiner's Action mailed November 26, 2007, having a shortened statutory period for response set to expire February 26, 2008. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by Office, to ensure full response on the merits to each finding of Office.

Claim Rejections - 35 U.S.C. § 102

Claims 1-4, 6-10, and 12-16 stand rejected under 35 U.S.C. § 102(a), as being anticipated by Dengler, et al. (Herz 2000, 7: 598-610).

Every element of the claim must be found in a single prior art reference for an application to be rejected for anticipation.¹ Further, the prior art must enable, or describe, "the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention[.]"² without undue experimentation³. Further, the invention must carry out the same function.⁴

Claims 1-4, 6-10, and 12-16, 35 U.S.C. § 102(a)

Office has rejected claims 1-4, 6-10, and 12-16, under 35 U.S.C. § 102(a), as anticipated by Dengler, et al. (Herz 2000, 7: 598-610). Office stated that Dengler teaches a treatment method for myocardial infarction through administration of umbilical cord blood cells directly into the heart tissue or systemically.⁵ Dengler, in general, is a review summary of stem cell and precursor cell mobilization, the majority of which do not address UCB cells.⁶ Figure 1 addresses bone marrow stem cells and endothelial progenitor cells, not UCB cells,⁷ as required by claim 1.⁸ Thus, Figure 1 does not disclose every element of claim 1 and, under MPEP 2131, does not

¹ See, MPEP 2131, citing Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

² Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., 468 F.3d 1366, 1383 (Fed. Cir. 2006).

³ MPEP 2121.01.

⁴ National Business Systems, Inc. v. AM Intern., Inc., 743 F.2d 1227, 1235 (7th Cir. 1981) (Quoting Popell Bros., Inc. v. Schick Electric, Inc., 494 F.2d 162, 164 (7th Cir. 1974)).

⁵ Office Action, dated June 27, 2007, page 3.

⁶ See, T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, pages 601, column 2 to page 603 (adult stem cells); pages 603-604 (embryonic stem cells); pages 604-605 (skeletal myoblasts); pages 605-606 (endothelial precursor cells).

⁷ See, T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 601, column 1, figure legend for Figure 1, especially lines 3-4.

anticipate claim 1. Dengler states that umbilical cord blood has potential plasticity to differentiate, that is similar or greater to adult stem cells. Dengler goes on to state cardiac transplantation studies using UCB “seem warranted.”⁹ However, Dengler does not discuss UCB transplantation further. Claim 1 requires the treatment of cardiomyopathy, myocardial infarction, and congenital heart disease by administering an umbilical cord blood composition.¹⁰ Dengler fails to discuss delivery of UCB cells and fails to anticipate the current invention, pursuant to MPEP 2131.

Dengler also fails to anticipate the current invention as Dengler does not enable the current invention. Dengler fails to provide any information on the administration of umbilical cord blood cells, the amount of cells needed, the administration method (i.e. systemically, surgically), or administration composition¹¹, other than to state “experimental studies of cord blood stem cells for cardiac replacement therapy ... seem warranted.”¹² For a prior art reference to anticipate an invention, the reference must enable “the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention[.]”¹³ Dengler does not provide sufficient information for one of skill in the art to administer HUCBC cells to treat a circulatory disorder, as defined and limited by claim 1.

Dengler does not provide sufficient information to carry out circulatory disease treatment, such that an individual skilled in the art would be capable of treating a patient with umbilical cord blood cells. Therefore, the elements of independent claim 1 and independent claim 12 are not covered in a single reference, and claims 1 and 12 cannot be anticipated. As such, the claims dependent on claims 1 and 12 are also patentable. Accordingly, it is respectfully requested that the rejection of claims 1, 3, 6-10, 12, and 14-16 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Applicant acknowledges Office has rejected claims 5, 11, 17, and 18 under 35 U.S.C. § 103(a), as being unpatentable.

⁸ See amended paragraph [c1], page 2, Amendment A, filed Sept. 27, 2007.

⁹ T. Dengler, H. Katus, “Stem Cell Therapy for the Infarcted Heart (“Cellular Cardiomyoplasty”),” Herz 7:598-610, 2002, page 604, column 2, lines 18-43.

¹⁰ See amended paragraph [c1], page 2, Amendment A, filed Sept. 27, 2007.

¹¹ See, T. Dengler, H. Katus, “Stem Cell Therapy for the Infarcted Heart (“Cellular Cardiomyoplasty”),” Herz 7:598-610, 2002, page 604, column 2, lines 18-43.

¹² T. Dengler, H. Katus, “Stem Cell Therapy for the Infarcted Heart (“Cellular Cardiomyoplasty”),” Herz 7:598-610, 2002, page 604, column 2, lines 35-39

¹³ Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., 468 F.3d 1366, 1383 (Fed. Cir. 2006).

To support a rejection under 35 USC §103(a), a *prima facie* case of obviousness must be made.¹⁴ In determining obviousness, all words of a claim must be considered.¹⁵ The prior art must suggest or motivate an individual in the art to modify or combine the references, a reasonable expectation of success must be present, and the teaching must teach or suggest all the claim limitations.¹⁶

Office has rejected claims 5, 11, 17, and 18 in light of Dengler et al., in view of Broxmeyer et al. (Proc. Nat. Acad. Sci., 1992, 89:4109-4113), Lim et al., (Bone Marrow Trans., 1999, 24:965-970), Anversa (US Pub.No. 2002/0061587 A1), and Edelberg, et al. (US Pub.No. 2003/0091547 A1).¹⁷

Applicant respectfully traverses Office's rejection as Dengler, Broxmeyer, Lim, and Edelberg do not teach the current invention and are not analogous art, and thus not prior art for the purposes of 35 U.S.C. § 103(a).¹⁸

Applicant respectfully disagrees that Dengler anticipates the invention, for the reasons stated *supra*. Dengler is a summary article on the understanding of cardiopulmonary therapy, as of 2002.¹⁹ As such, Dengler does not only address umbilical cord blood transplantation, but other therapies also. For example, Dengler addresses self regenerative bone marrow stem cell and endothelial progenitor cell mobilization and repair in Figure 1.²⁰ Dengler's discussion of umbilical cord blood is limited to one section.²¹ In the UBC discussion, Dengler states that, like embryonic stem cells,

the largest obstacle against the successful use of human embryonic stem cells to replace heart muscle will be the tissue incompatibility on the level of the HLA system.²²

¹⁴ MPEP 2143.

¹⁵ MPEP 2143.03.

¹⁶ See, MPEP 2143.

¹⁷ Office Action, dated June 27, 2007, page 5.

¹⁸ MPEP 2141.01(a)(I), (II) require the prior art to be analogous, meaning "either in the field of applicant's endeavor or, ... reasonable pertinent to the particular problem," relying on differences and similarities in structure and function.

¹⁹ T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 598, column 2, lines 1-9.

²⁰ T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 601, column 1, especially Figure 1 legend.

²¹ T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 604, column 2, lines 18-43.

²² T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 604, column 1, lines 17-20.

Dengler further states that “umbilical cord stem cells ... show few differences compared with embryonic stem cells regarding the use for cardiac regeneration[.]”²³ Hence, Dengler teaches that human umbilical cord blood currently cannot replace human heart tissue.

Broxmeyer mentions using stem cell engraftment of bone marrow to treat anemia and leukemia,²⁴ however, the focus of the Broxmeyer article is that the populating capacity of stem cells is related to colony forming unit (CFU-GM) testing.²⁵ Broxmeyer’s teachings address only bone marrow engraftment,²⁶ and therefore do not teach the use of umbilical cord blood in treatment of circulatory disorders, as defined by claim 1 and the specification.

Lim analyzed methods of quantifying hematopoietic potential of UCB, based on two popular quantification methods, CD34⁺ and HPC content.²⁷ Lim addresses the hematopoietic potential of UCBC, which is the ability to produce blood,²⁸ and also fails to teach the use of umbilical cord blood in treatment of circulatory disorders.

Prior art references must be considered in their entirety.²⁹ The combination of Dengler, Broxmeyer, Lim, Anversa, and Edelberg fail to teach the current invention. Both Broxmeyer and Lim teach the transplantation of the hematopoietic system, not circulatory disorders, as limited in claim 1. Therefore, Broxmeyer and Lim fail to teach the present invention and fail to obviate the invention. As discussed, *supra*, Dengler fails to anticipate the invention. Therefore, combining the references cannot anticipate the invention. Because the combination of Dengler, Broxmeyer, Lim, Anversa, and Edelberg fail to obviate claim 1, all claims dependent on claim 1 are likewise non-obvious.³⁰ Therefore, it is respectfully requested that Office reconsider claims, 11, 17, and 18 and withdraw the rejection under 35 U.S.C. § 103(a).

²³ T. Dengler, H. Katus, “Stem Cell Therapy for the Infarcted Heart (“Cellular Cardiomyoplasty”),” *Herz* 7:598-610, 2002, page 604, column 2, lines 24-29.

²⁴ H. Broxmeyer, et al. *Proc. Nat. Acad. Sci.*, 89:4109-4113, 1992, page 4112, column 1, lines 7-24.

²⁵ *Id.* at 411, 412, column 2.

²⁶ See, *Id.*, in general.

²⁷ F. Lim, et al., “The Number of Nucleated Cells Reflects the Hematopoietic Content of Umbilical Cord Blood fo Transplantation,” *Bone Marrow Transplantation*, 24:965-970, 1999, page 965, column 2 lines 34-46; 966 column 1, lines 1-2.

²⁸ <http://www.medterms.com/script/main/art.asp?articlekey=31270> (searched hematopoietic) (last accessed Dec. 26, 2007). The hematopoietic system is the group of organs involved in producing blood, specifically the bone marrow, spleen, tonsils, and lymph nodes. <http://www.thefreedictionary.com/hematopoietic+system> (last accessed Dec. 26, 2007).

²⁹ MPEP 2141.02.

³⁰ MPEP 2143.03.

Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

SMITH & HOPEN



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CERTIFICATE OF ELECTRONIC TRANSMISSION

(37 C.F.R. 2.190 (b))

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